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In the Supreme Court of the United States

OCTOBER TERM, 1961

No. 929

ELLIS RESEARCH LABORATORIES, INC., a corporation, and ROBERT W. ELLIS, an individual, PETITIONERS

v.

UNITED STATES OF AMERICA

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE SEVENTH CIRCUIT

BRIEF FOR THE UNITED STATES IN OPPOSITION

OPINIONS BELOW

The opinion of the Court of Appeals (Pet. 29-37) is not yet reported. The findings, conclusions and judgment of the United States District Court for the Northern District of Illinois appear at R. 332-342.[1]

[1] "R." references are to the appendix as filed by appellant (petitioner) in the court below; "A.R." references are to appellee's appendix in the Court of Appeals.

JURISDICTION

The judgment of the Court of Appeals was entered on March 22, 1962. The petition for a writ of certiorari was filed on May 2, 1962. The jurisdiction of this Court is invoked under 28 U.S.C. 1254(1).

QUESTIONS PRESENTED

1. Whether an instrument or device which is found to be worthless and to have been sold to chiropractors by false labeling claims as to its diagnostic capabilities is exempt from the Federal Food, Drug, and Cosmetic Act under a proviso which authorizes the Secretary to promulgate regulations exempting certain drugs and devices from bearing adequate directions for use.

2. Whether petitioners were entitled as of right to a jury trial in a suit for an injunction to restrain violations of the Federal Food, Drug, and Cosmetic Act.

3. Whether the injunction could properly restrain, in addition to false labeling, shipping the device in commerce unless accompanied by matter stating the use for which the article is intended.

STATUTE AND REGULATIONS INVOLVED

The Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 301 et seq., provides in pertinent part:

Section 201 (21 U.S.C. 321)

For the purposes of this Act—

* * * * *

(h) The term "device" * * * means instruments, apparatus, and contrivances, including their components, parts, and accessories, intended (1) for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; or (2) to affect the structure or any function of the body of man or other animals.

* * * *

(m) The term "labeling" means all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article.

Section 301 (21 U.S.C. 331)

The following acts and the causing thereof are hereby prohibited:

(a) The introduction or delivery for introduction into interstate commerce of any * * * device * * * that is * * * misbranded.

Section 302 (21 U.S.C. 332)

(a) The district courts of the United States and the United States courts of the Territories shall have jurisdiction, for cause shown, * * * to restrain violations of section 301, * * *

(b) In case of violation of an injunction or restraining order issued under this section, which also constitutes a violation of this Act, trial shall be by the court, or, upon demand of the accused, by a jury. * * *

Section 502 (21 U.S.C. 352)

A drug or device shall be deemed to be misbranded—

(a) If its labeling is false or misleading in any particular.

* * * *

(f) Unless its labeling bears (1) adequate directions for use; * * *: *Provided*, that where any requirement of clause (1) of this paragraph, as applied to any drug or device, is not necessary for the protection of the public health, the Secretary shall promulgate regulations exempting such drug or device from such requirement.

21 C.F.R. 1.106 and Cum. Supp. (Jan. 1, 1961)
Drugs and Devices; directions for use.

* * * *

(d) *Exemption for prescription devices.* A device which, because of any potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use, is not safe except under the supervision of a practitioner licensed by law to direct the use of such device, and hence for which "adequate directions for use" cannot be prepared, shall be exempt from section 502(f)(1) of the act if all the following conditions are met:

(1) The device is:

(i)(a) In the possession of a person (or his agents or employees) regularly and lawfully engaged in the manufacture, transportation, storage, or wholesale or retail distribution of such device; or

(b) In the possession of a practitioner, such as physicians, dentists, and veterinarians, licensed by law to use or order the use of such device; and

(ii) Is to be sold only to or on the prescription or other order of such practitioner for use in the course of his professional practice.

(2) The label of the device (other than surgical instruments) bears:

(i) The statement "Caution: Federal law restricts this device to sale by or on the order of a .....," the blank to be filled with the word "physician," "dentist," "veterinarian," or with the descriptive designation of any other practitioner licensed by the law of the State in which he practices to use or order the use of the device; and

(ii) The method of its application or use.

(3) The labeling of the device (which may include brochures readily available to licensed practitioners) bears information as to the use of the device by practitioners licensed by law to use it or direct its use: *Provided, however,* That such information may be omitted from the labeling if it is contained in scientific literature widely disseminated among practitioners licensed by law to use or order the use of such device.[2]

(4) Any labeling, as defined in section 201 (m) of the act, whether or not it is on or within a package from which the device is to be dispensed, distributed by or on behalf of the manufacturer, packer, or distributor of the device, that furnishes or purports to furnish information for use of the device contains adequate in-

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[2] This paragraph was amended on August 28, 1961, to require full disclosure of all uses and hazards of prescription devices in labeling on or within the dispensing package. 26 F.R. 8389.

formation for such use, including indications, effects, routes, methods, and frequency and duration of administration and any relevant hazards, contraindications, side effects, and precautions, under which practitioners licensed by law to employ the device can use the device safely and for the purposes for which it is intended, including all purposes for which it is advertised or represented. This information will not be required on so-called reminder-piece labeling which calls attention to the name of the device but does not include indications or other use information.

(5) All labeling, except labels and cartons, bearing information for use of the device also bears the date of the issuance or the date of the latest revision of such labeling.

STATEMENT

The United States initiated this action under Section 302 of the Food, Drug, and Cosmetic Act to enjoin the interstate distribution of an electrical device, intended for use in the diagnosis of disease in man, alleged to be misbranded because of false and misleading representations in promotional and instructional literature concerning its capability to diagnose a wide variety of diseases and abnormal conditions. (R. 3-14). Petitioners denied the allegations (R. 14-21) and demanded a jury trial. (R. 22-28). On the Government's motion, the jury demand was stricken. (R. 29). The case was tried, and a permanent injunction issued. (R. 332-342). The Court of Appeals for the Seventh Circuit affirmed the decree. (Pet. 37).

A. The device

The Micro-Dynameter is a galvanometer mounted in a metal cabinet. On its face is a scale or meter to measure in milliamperes the flow of current, together with a number of dials which can be set at numbered or lettered positions. The dial settings increase or decrease the resistance to the current flowing through the machine. The current which flows, and is measured by the scale or meter, is generated by closing the circuit between two dissimilar metal "probes". The circuit is closed by placing the "probes" at different points on the human body, by placing the "probes" together, or by immersing them in water. No outside source of electricity is utilized except in the calibration procedure. (R. 69-72, 163-165, 167).

In actual operation, the machine is first supposed to be "calibrated" in an effort to insure consistent results. (R. 166-167). The patient then holds in his hand a combination electrode (or "probe") consisting of a silver pole and a zinc pole. (Ex. 2A, p. 8). A lighted needle then moves across the scale on the face of the device. (R. 168). The reading obtained, according to petitioners, is the "Potential Energy" or "vital reserve" of the body. (Ex. 2A, p. 7). A second reading, obtained by adjusting the knobs on the face of the cabinet, is the "Metabolic Index", and supposedly measures the "exchange rate of cellular waste and nutriment" in the body. (Ex. 2A, p. 7). The final reading, obtained with the same knob settings as the "Metabolic Index", but after the patient takes a deep breath, is the "Oxygenation Index". (Ex. 2A, p. 8).

These readings are recorded on a card (Ex. 2B and Def. Ex. M, R. 324), and by constructing lines between the points indicated two other values are obtained—the "Dynamic Energy" and the "Health Index". These are claimed to show the general state of the health of the body. (Ex. 2A, p. 7, R. 167-169).

With an electrode of antimony alloy placed on the tongue and an iron electrode on the arm, the patient's "Acid Alkaline Balance" is determined. (Ex. 2A, p. 15, R. 169). And in still other tests, one electrode is held in the patient's hand and the other moved over various areas of the body. (Ex. 2A, p. 15, R. 169-171). High readings are claimed to indicate areas of pathology.

B. The evidence as to false labeling

In general, the claims for the machine are that it can discover changes in living tissue by measuring electrical current produced by such tissue changes. (Ex. 2C, p. 4). The government's evidence was designed to show that the current measured is not generated by the human body at all. It arises from the contact of two dissimilar metals on moist substances—skin or a wet towel (R. 96). When the electrodes were immersed in tap water, a reading of 100 on the "Potential Energy" scale was obtained. (R. 170-171).

An electronics engineer analyzed the electrical circuitry of the machine (Ex. 13, R. 70-72) and described its behavior. He explained several factors which influence the readings on this device, such as washing the hands in water, alcohol, or acetone; drying, clapping, or spanking the hands; holding the

hands over the head; or placing the localized electrode near a large vein or an artery. (Ex. 13, pp. 2, 4, R. 72). His test showed that all readings would be affected if a fresh battery were not used in the calibration procedure. (Ex. 13, pp. 2-3).

Two qualified physicians, who had studied the machine, testified that it had no usefulness at all in the diagnosis of disease. (R. 76, 87). Indeed, tests on two cadavers (Ex. 15B, 15C) yielded "Potential Energies" of 90 and 85, "Metabolic Index" of 15 and 10, and in one case (Ex. 15C) an Acid Alkaline Balance of 16. Normal "Potential Energy" is 100, and all readings are supposed to "drop to zero at death". (Ex. 2C, p. 6).

Finally, two physician-witnesses expert in electro-diagnostic equipment, such as the electro-cardiograph and electroencephalograph, testified that the Micro-Dynameter was in no sense comparable, that the readings obtained from it were meaningless, and that such terminology as "Potential Energy" and "Metabolic Index", as used with this machine, had no relation to potential energy or metabolism as those terms are generally understood in the scientific community. (R. 110-121, 144-148).

C. The findings of the trial court and the injunction

The trial court found that the current flowing through the device "is not dependent on the health or diseased condition of the body" but is influenced by "perspiration on the skin and other similar factors" (Finding 4, R. 333); and that the device was not adequate or effective for diagnosing disease. (Find-

ings 7-8, R. 336-338). The court found also that, unless enjoined, the petitioners would continue to distribute the Micro-Dynameter either with labeling that falsely represented its usefulness in diagnosis or with labeling which failed to state the conditions for which it was intended. (Finding 10, R. 339).

The injunction issued by the court (R. 340-342) restrained petitioners from introducing the machine in commerce with the type of labeling described in the findings and prohibited, additionally, the introduction of the device in commerce

> * * * unless such device bears or is accompanied by written, printed, or graphic matter which clearly states every disease, condition, symptom and purpose for which the article is intended to be used and for which it is represented by any means to the public; * * *

ARGUMENT

1. Petitioners argue that, because the device is sold to chiropractors and physicians, it is exempt from the requirements of the Food, Drug and Cosmetic Act, relying specifically upon 21 U.S.C. 352(f)(1) which authorizes the Secretary, by regulation, to exempt devices from the requirement of adequate directions for use. A short answer to this argument is that the statute confers no exemption for false representations to chiropractors or any other medical practitioners, but, on the contrary, provides that all drugs and devices shall be deemed to be misbranded if their labeling is false or misleading in any particular. Diagnostic equipment of this kind must be honestly

represented to prospective purchasers, including licensed practitioners, for whom it is intended.

Section 502(f)(1) (*supra*, p. 3) provides for exemption, established by regulations, only from the requirement that a device bear adequate directions for use. It has no bearing upon a charge brought on the basis of false and misleading labeling under Section 502(a). Even if the device were exempt and the petitioners could have omitted directions for use from the label, the fact is that they did not omit such directions; promotional and instructional literature was sent. It is because these directions and instructional material were shown to be false and misleading, that the device was properly found to be misbranded.

Moreover, even if Section 502(f)(1) were applicable, petitioners have not shown that the Micro-Dynameter meets the conditions upon which the exemption depends. The statute, as noted, does not provide the exemptions, but directs the Secretary to promulgate regulations exempting any drug or device from the "adequate directions" requirement where it "is not necessary for the protection of the public health". The Secretary has promulgated regulations exempting drugs and devices which can be safely used only by professionally trained people from the requirement of adequate directions for use, but this exemption is conditioned upon other labeling directed to the professional users which will enable them safely and effectively to use the drug or device. Petitioner's device, being worthless, is not one that can be used safely and effectively by the medical profession. Nor does it meet the labeling requirements

that are imposed by the exempting regulations. See *supra*, p. 5.

2. There is no substance to the claim that petitioners were entitled as of right to a jury trial in this action for an injunction. The proceeding is a statutory one, unknown to the common law, and is, of course, equitable in nature. Cf. *Porter* v. *Warner Holding Co.*, 328 U.S. 395, 397-398; *Mitchell* v. *Robert De Mario Jewelry, Inc.*, 361 U.S. 288, 292. In contrast to the specific provision for jury trial in the seizure provision of the Act, 21 U.S.C. 334, the statute makes no provision for jury trial in an enforcement proceeding to restrain violations, 21 U.S.C. 332.

3. As set forth in the Statement, *supra*, petitioners are enjoined not only from distributing the device with the type of misbranding shown to have been used, but also restrained from introducing the device in commerce unless accompained by matter stating every disease and purpose for which it is represented to be useful.

It was reasonably anticipated by the trial court (Finding 10, R. 339) that if the petitioners were

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The decision of the court below is not in conflict with *Brückman* v. *Hollzer*, 152 F. 2d 730 (C.A. 9), and *Leimer* v. *Woods*, 196 F. 2d 828 (C.A. 8). Nor is it contrary to the ruling of this Court in *Dairy Queen, Inc.* v. *Wood*, No. 244, this Term, decided April 30, 1962. In each of those cases, the plaintiff had joined prayers for legal and equitable relief in the same action, with issues of fact common to the legal and equitable claims. The rulings protected the right to a jury trial on the issues of fact involved in the suit at law even though the issues were also involved in the equitable action.

enjoined only from using false representations in the promotion of the device, the firm would continue to distribute the Micro-Dynameter without any labeling whatever and without directions as to the function of the article and the manner of its use. This practice would be equally violative of the Federal Food, Drug and Cosmetic Act. Section 502(f) requires a drug or device to be labeled with "adequate directions for use." The courts have consistently held that "adequate directions for use" must include statements of all purposes for which the device is intended by its shipper. *United States* v. *Hohensee*, 243 F. 2d 367 (C.A. 3), certiorari denied, 353 U.S. 976; *Irons* v. *United States*, 244 F. 2d 34, 44 (C.A. 1), certiorari denied, 354 U.S. 923; *Alberty Food Products* v. *United States*, 194 F. 2d 463 (C.A. 9). The scope of the injunction, therefore, is only as broad as necessary to assure compliance with the Act. Certainly, an injunction may reach "like or related" actions which may "fairly be anticipated from the defendant's conduct in the past". *National Labor Relations Board* v. *Express Publishing Company*, 312 U.S. 426, 435-6. A decree is not subject to objection because it was framed "to suppress the unlawful practices and to take such reasonable measures as would preclude their revival," *Ethyl Gasoline Corp.* v. *United States*, 309 U.S. 436, 461.

The claim that the injunction lacks specificity is without merit. The injunction does not enjoin violations "as charged in the Complaint"; nor does it simply enjoin violations of the Act in general terms. The injunction restrains the petitioners from dis-

tributing the Micro-Dynameter or any similar therapeutic device with certain specific false and misleading claims, and it further enjoins the petitioners from interstate distribution of the device in a way which constitutes misbranding because of a failure to bear adequate directions for use. (R. 340-342). Petitioners can be under no illusions as to what is forbidden.

CONCLUSION

The decision below is clearly correct and the petition for a writ of certiorari should be denied.

ARCHIBALD COX,
Solicitor General.

HERBERT J. MILLER, JR.,
Assistant Attorney General.

BEATRICE ROSENBERG,
Attorney.

HAROLD W. HOROWITZ,
Associate General Counsel,

WILLIAM W. GOODRICH,
Assistant General Counsel,
Department of Health, Education,
and Welfare.

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